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APPLICATION NO	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO	CONFIRMATION NO
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EXAMINER

MAHATAN, CHANNING

ART UNIT PAPER NUMBER

1631

DATE MAILED 02 26 2003

98

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/663,968

Applicant(s)

YIP, PING

Examiner

Channing S. Mahatan

Art Unit

1631

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 21 November 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 1-45 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 1-45 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☒ The proposed drawing correction filed on 10 September 2002 is: a) ☒ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.

2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-946)

3) ☒ Information Disclosure Statement(s) (PTO-1449)

1 Sheet

5) ☐ Notice of Informal Patent Application (PTO-11)

6) ☐ Other

DETAILED ACTION

APPLICANTS ARGUMENTS

Applicants' arguments in Paper No. 12, filed 21 November 2002, have been fully considered but they are not deemed to be persuasive for the reasons set forth below. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

CLAIMS UNDER EXAMINATION

Claims herein under examination are claims 1-45.

Claims Rejected Under 35 U.S.C. § 112 1st Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized in Ex parte Forman, 230 U.S.P.Q. 546 (B.P.A.I. 1986) and reiterated by the Court of Appeals in In re Wands, 8 U.S.P.Q.2d 1400 at 1404 (C.A.F.C. 1988). The factors to be considered in determining whether undue experimentation is required include: (1) the quantity of experimentation necessary, (2) the amount or direction presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. The Board also stated that although the level of skill in

Art Unit: 1631

While all of these factors are considered, a sufficient amount for a *prima facie* case are discussed below.

LACK OF ENABLEMENT

Claims 1-45 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The following steps in claims 1, 38, 40, 41, and all claims dependent therefrom: "correcting the baseline", "removing the residual baseline from the intermediate data set", and "locating a probable peak" is not enabled and thus failing to provide guidance to practice. The following indicate the particularly pages and line numbers within the specification for which each of the above said steps fail to provide an enabling disclosure:

Claim 1 (line 6), 38 (line 8), 40 (line 5), 41 (line 9), and all claims dependent therefrom recite the step "correcting the baseline" which is not enabled. The specification indicates that "A baseline correction substantially corrects the data to remove a component of the data attributable to the test system, and sample preparation characteristics", however absent are the components attributable to the test system nor components attributable to the sample preparation characteristics (page 8, lines 13-21 of the Specification).

Claim 1 (line 11), 38 (line 13), 40 (line 10), and all claims dependent therefrom recite the step "removing the residual baseline from the intermediate data set" which is not enabled. The specification indicates that "A quartic polynomial is applied ... to generate a residual baseline ...

Art Unit: 1631

however, absent is the applied quartic polynomial (page 18, lines 16-18 of the Specification; Figures 24 and 25). Absent from the specification is the applied quartic polynomial applied which is required to generate a residual baseline. Thus, without the quartic polynomial one of skill in the art would not understand how to perform the step because of the lack of guidance within the original disclosure to generate a residual baseline and thus, remove said residual baseline from the intermediate data set.

Claim 1 (line 13), 38 (line 15), 40 (line 12), 41 (line 12), and all claims dependent therefrom recite the step of "locating a probable peak" which is not enabled. The specification indicates that "...it is therefore known where peaks indicating composition should be located ... knowing the location of these expected peaks ... the method ... matches putative peaks in the processed signal to the location of the expected peaks ... the probability of each putative peak in the data being an actual peak indicative of the composition of the biological sample can be determined. Once the probability of each peak is determined ... the method ... statistically determines the composition of the biological sample, and determines if confidence is high enough to calling a genotype." "As the set of possible compositions in the biological sample is known before the mass spectrometry data is generated, the possible positioning of expected peaks is already known. These possible peaks are referred to as expected peaks...". However, absent from the specification are the set of possible compositions and hence absent are the expected peak (page 9, lines 16-24; page 17, lines 7-10; and page 20, lines 13-18 of the specification). Without the set of possible compositions (i.e. expected peaks), known prior to the generation of mass spectrometry data, one of skill in the art would be unable to match the

Art Unit: 1631

putative peaks with the expected peaks thereby determining the probability of each putative peak in the generated data to be an actual peak indicative of the composition of the biological sample.

Claims 1-45 while being enabling for the disclosed "generating a data set", "denoising the data set", "defining putative peaks", "remove residual baseline effects", and "compressing the intermediate data set", does not reasonably provide enablement for "generating a data set", "denoising the data set", "defining putative peaks", "remove residual baseline effects", and "compressing the intermediate data set" by any other means. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. The following indicate the particularly pages and line numbers within the specification for which each of the above said steps are enabled for but are not commensurate with the specification:

Claim 1 (line 3), 38 (line 3), 41 (line 3), 45 (line 3), and all claims dependent therefrom "generating a data set", however, the specification indicates that the generated "data is indicative of the mass of DNA fragments in the sample" (pages 6-7, lines 10-25 and 1-20, respectively of the Specification). The specification fails to provide for other means for "generating a data set". No other methods for "generating a data set" are present and none appear to have been known in the art. No guidance, direction, or examples are provided such that one of ordinary skill in the art would have known how to practice the claimed invention.

Claim 1 (line 5), 38 (line 7), 40 (line 4), 41 (line 7), and all claims dependent therefrom "denoising the data set", however, the specification indicates the "denoising process generally entails 1) performing a wavelet transformation on the raw data to decompose the raw data into

Art Unit: 1631

coefficients; and 3) applying a scaled noise profile to other stages in the wavelet transformation.” (beginning on page 10, line 13 through page 14, line 12 of the Specification). The specification fails to provide for other means for “denoising the data set”. No other methods for “denoising the data set” are present and none appear to have been known in the art. No guidance, direction, or examples are provided such that one of ordinary skill in the art would have known how to practice the claimed invention.

Claim 1 (line 8), 38 (line 10), 40 (line 7), and all claims dependent therefrom “defining putative peaks”, however, the specification indicates that “The putative peak areas are located in the denoised and shifted signal, wherein the putative peak areas are systematically identified by taking a moving average along the signal and identifying sections of the signal which can exceed a threshold related to the moving average (page 14, lines 14-16 of the Specification; page 17, lines 15-17 of the Specification). The specification fails to provide for other means for “defining putative peaks”. No other methods for “defining putative peaks” are present and none appear to have been known in the art. No guidance, direction, or examples are provided such that one of ordinary skill in the art would have known how to practice the claimed invention.

Claim 1 (line 9), 38 (line 11), 40 (line 8), 41 (line 11), 45 (line 9), and all claims dependent therefrom recite the step to “remove residual baseline effects”. however, the specification indicates that in order “To remove the residual baseline effects ... the putative peaks ... are removed from the baseline corrected signal. The peaks are removed by identifying a centerline ... of the putative peaks ... and removing an area both to the left and to the right of the identified centerline. For each putative peak, an area equal to twice the width (W) of the

Art Unit: 1631

removed from the right of the center line.” (page 18, lines 4-9 of the Specification; Figure 22).

The specification fails to provide for other means to “remove residual baseline effects”. No other methods to “remove residual baseline effects” are present and none appear to have been known in the art. No guidance, direction, or examples are provided such that one of ordinary skill in the art would have known how to practice the claimed invention.

Claim 19 (line 2) and all claims dependent therefrom recite “compressing the intermediate data set”, however, the specification indicates “The first point of the intermediate data file becomes the starting point for the compressed data. Thereafter each data point in the compressed data ... is calculated as follows: the whole number portion (left of the decimal) is replaced by the difference between the current and the last whole number. The remainder (right of the decimal) remains intact.” (page 16, lines 5-8 of the Specification). The specification fails to provide for other means to “compressing the intermediate data set”. No other methods to “compressing the intermediate data set” are present and none appear to have been known in the art. No guidance, direction, or examples are provided such that one of ordinary skill in the art would have known how to practice the claimed invention.

Claims Rejected Under 35 U.S.C. § 112 2nd Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. § 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-45 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

VAGUE AND INDEFINITE

Claim 1 (lines 3-4), 38 (lines 3-4), 40 (lines 2-3), 41 (lines 3-4), 45 (lines 3-4), and all claims dependent therefrom recites the phrase “compositional data regarding the biological sample”/“data set indicative of the composition of the biological sample”/“data set indicative of the component in the biological sample” which is vague and indefinite. It is unclear by what limitation applicant refers to as “compositional data”/“composition”/“component”, particularly for a biological sample (i.e. sequence, enzymatic activity, etc). Applicant can resolve this issue by particularly pointing out what the limitations of “compositional data”/“composition”/“component” refers that it utilized in the method. Clarification of the metes and bounds of the limitation, via clearer claim wording, is required.

Claim 45 (line 16) recites the phrase “responsive to the calculated probability” which is vague and indefinite. It is unclear by what limitation applicants refer to as “responsive”, wherein “responsive” implies a degree of responsiveness (i.e. a value, criteria, etc). Applicants can resolve this issue by particularly pointing out what the limitations of “responsive to the calculated probability” refers to. Clarification of the metes and bounds of the limitation, via clearer claim wording, is required.

No Claims Are Allowed.

EXAMINER INFORMATION

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located

Art Unit: 1631

Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 C.F.R. § 1.6(d)). The CM1 Fax Center number is either (703) 308-4242 or (703) 305-3014.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Channing S. Mahatan whose telephone number is (703) 308-2380. The examiner can normally be reached on M-F (8:30-5:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael P. Woodward, Ph.D., can be reached on (703) 308-4028.

Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instruments Examiner, Tina M. Plunkett, whose telephone number is (703) 305-3524 or to the Technical Center receptionist whose telephone number is (703) 308-0196.

Date: *February 24, 2003*

Examiner Initials: *CSM*

Marianne P. Allen
MARIANNE P. ALLEN
PRIMARY EXAMINER
~~GROUP 100~~
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